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August 26, 1999

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Ms. Felicia Satchell  
Chief, Food Standards Branch  
Food and Drug Administration  
Office of Food Labeling (HFS-158)  
Center for Food Safety and Applied Nutrition  
200 C Street SW  
Washington, DC 20204

Re: Revised Labels for Sartori TMP

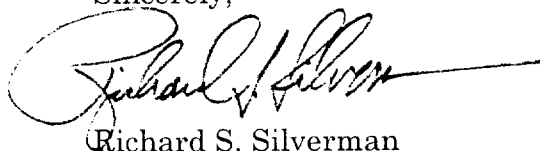
Dear Ms. Satchell:

We are enclosing labels with the changes the agency has recommended as part of its review of the June 29, 1999 request for a temporary marketing permit (TMP) submitted by our client, Sartori Foods (Sartori). In its TMP, Sartori seeks authorization to market a Parmesan cheese that has been aged for six months rather than the 10 months required by the standard of identity. As part of its review of that TMP, FDA requested minor modifications to the labels for these products.

The enclosed labels reflect the changes recommended by the agency. Specifically, the net weight statements have been revised to eliminate the ".0" from the declaration (*i.e.*, the declaration is "5 LBS" rather than "5.0 LBS"). The UPC code on the revised labels also has been tilted 90 degrees so that it forms a vertical rather than a horizontal, column.

If you have any questions, please feel free to contact us.

Sincerely,



Richard S. Silverman

Enclosures

cc: Wayne R. Casper

99P-4648

LETI

BRUSSELS BUDAPEST\* LONDON MOSCOW PARIS\* PRAGUE\* WARSAW

BALTIMORE, MD COLORADO SPRINGS, CO DENVER, CO LOS ANGELES, CA MCLEAN, VA NEW YORK, NY ROCKVILLE, MD

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\*Affiliated Office



The Flavor and Performance Specialists

Rec'd  
7/1/99

JAMES C. SARTORI  
President and  
Chief Executive Officer

June 29, 1999

Ms Felicia Satchell  
Chief, Food Standards Branch  
Food and Drug Administration  
Office of Food and Labeling (HFS-158)  
Center for Food Safety and Applied Nutrition  
200 C. Street SW  
Washington DC 20204

Subject: Request for Issued Temporary Permit for Grated Parmesan Cheese Aged for 6 Months under 21CFR §130.17

Dear Ms Satchell:

The attached application requests the issuance of a temporary marketing permit to market and sell grated Parmesan cheese aged for 6 months under 21CFR § 130.17. The sole purpose of this test is to obtain support necessary to amend the age standard for Parmesan cheese--established at 'not less than 10 months' in 21CFR § 133.165.

We request this temporary permit to test market grated Parmesan cheese that is made from Parmesan cheese using the make procedure described in the Parmesan Standard 21CFR § 133.165 (b)---through the use of a safe and suitable cheese curing enzyme. The resulting product is a six-month aged Parmesan cheese that has the taste, texture and functional characteristics of Parmesan cheese aged for 10 months. This product complies with all of the requirements found in the standard of identity established for Parmesan cheese in 21CFR § 133.165--with the exception of age.

Importantly, our proposed 6-month Parmesan is made by the procedures described in the Parmesan Standard found at 21CFR § 133.165. To achieve the taste, texture and functional characteristics of a Parmesan that has been aged for 10 months, we have added an additional safe and suitable enzyme. This enzyme has been affirmed as generally recognized as safe (GRAS) for use in foods, including cheese. We have attached a copy of our make procedure for the Parmesan cheese that is aged for 6 months. It is

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referenced as Exhibit (A) in the attachments. This make procedure and the referenced enzyme is proprietary and should be treated by FDA as confidential business information.

The basis for our applying for a temporary permit to market grated Parmesan cheese aged for 6 months is as follows:

1. We have long felt that the basis of having a 10-month aging requirement on Parmesan cheese was based more upon historical precedent than anything to do with food safety issues. Parmesan at 6 months of age is equally safe, from a food safety standpoint, to Parmesan cheese at 10 months of age.
2. Through use of an alternative safe and suitable cheese-making enzyme, we have, in 6 months, duplicated the organoleptic properties of our current Parmesan cheese aged for 10 months. In the development process for making this product, Sartori Food Corporation incorporated a number of research steps to ensure that this Parmesan cheese of 6 months of age has a comparable taste, texture, and nutritional equivalence to our current Parmesan cheese aged for 10 months. We have met this challenge. Internal sensory analysis utilizing trained panelists and outside nutritional analysis confirm that our proposed 6-month aged product has the same taste, texture, and nutritional characteristics as our 10-month aged Parmesan cheese. A summary of the sensory analysis is included with this application and is identified as Exhibit (B). Externally conducted nutritional analyses demonstrating both the nutritional equivalency of the two products and a comparison to competitive Parmesan cheeses aged 10 months is included as Exhibit (C). These data confirm that the Parmesan cheese aged for 6 months is nutritionally equivalent to products aged for 10 months.
3. A six-month curing process for Parmesan cheese that yields a taste and functionally equivalent product to Parmesan aged for 10 months provides a benefit to the cheese manufacturer and ultimately the user/consumer. The aging cycle is reduced by four months. This takes considerable costs out of the total manufacturing and curing process.

With this as background, we submit the following application which follows the requirements set forth in 21CFR § 130.17 for a temporary permit to market Parmesan cheese aged for 6 months which is equal in all aspects to the standard of identity for Parmesan cheese with the exception of aging.

We similarly ask that, if granted, the TMP take effect immediately upon date of issuance.

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In keeping with the regulations, it would be our intent, that after the completion of the temporary permit testing period, we would also submit a petition to change 21CFR § 133.165 as to the standard of identity for Parmesan cheese--requesting amendment of the aging provision from 'not less than 10 months' to 'not less than 6 months'.

Thank you for your prompt and attentive consideration of this petition and application. Application specifics for a temporary permit as outlined in 21CFR § 130.17 follow on the enclosed attachment. Please feel free to contact me at 920-893-6061 Ext. 310 if you need any further information.

Respectfully submitted,



James C. Sartori  
President and CEO  
Sartori Food Corporation

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**Application for A Temporary Permit for Market Testing Under 21 CFR § 130.17:  
To Test Grated Parmesan Cheese Deviating From The Standard of Identity As To  
Aging.**

**Name and Address of Applicant:**

Sartori Food Corporation, a manufacturer and converter of Italian cheeses, located at:  
107 Pleasant View, P.O. Box 258, Plymouth, WI 53073  
Telephone Number: 920-893-6061

**Producing The Food Involved:** Sartori Food Corporation is regularly engaged in the manufacture and sale of grated Parmesan cheese to the food service and ingredients market places--where our Parmesan cheese is used as a restaurant menu ingredient in the Food Service channel; and as a food ingredient for retail food manufacturers in the Ingredients or Industrial channel.

**Reference to Applicable Standards:** Sartori Food Corporation requests a temporary permit to market test grated Parmesan cheese aged for 6 months versus Parmesan cheese aged for 10 months. The applicable standard for Parmesan cheese is listed in 21 CFR § 133.165. The applicable standard for grated cheese is listed in 21 CFR § 133.146.

**A Full Description of the Proposed Variation:** The proposed grated Parmesan cheese we wish to market will conform to the Parmesan cheese standard in every respect--except as to age. It will continue to be made by a general procedure set forth in § 133.165 (b) for Parmesan cheeses. It will retain its characteristic granular, Parmesan texture. It will grate readily. It will contain no more than 32% moisture, and its solids will contain not less than 32% of milkfat, as determined by the method prescribed in § 133.5 (a), (b), and (d). Only as to curing time--6 months versus the currently required 10 months--will it deviate from the existing Parmesan cheese standard. Our method for making this product is attached as Exhibit A.

**Basis on Which Food is Believed to be Wholesome:** The grated Parmesan cheese aged for 6 months for which we request the temporary permit is the same as our current Parmesan cheese aged for 10 months as to flavor, texture, and nutritional characteristics.

It is also as wholesome as Parmesan cheese aged for 10 months or for that matter other cheeses currently being marketed in the retail, food service and ingredients market places.

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Internal sensory evaluation indicates that our Parmesan cheese aged for 6 months is judged organoleptically equivalent to our Parmesan cheese aged for 10 months across a range of attributes normally used to evaluate Parmesan cheese. (See Exhibit B)

We also tested for nutritional equivalency utilizing a respected, independent outside laboratory, MVTL Laboratories, 1126 N. Front Street, New Ulm, MN 56073-0249. The chemical analyses showed that our Parmesan cheese aged for 6 months was judged nutritionally equivalent on RDI or DRV (daily) values to our current Parmesan aged 10 months-- relative to fat, protein, calcium, sodium, and other nutritional characteristics. We also compared the six month aged Parmesan cheese to two competitive products and found comparable nutritional profiles. (See Exhibit C) Our Parmesan cheese aged for 6 months also complied with the current standard of identity requirements for Parmesan cheese, with the exception of the aging requirement.

The product itself has the same nutritional characteristics as Parmesan cheese aged for 10 months and is as wholesome and nondeleterious as the current standard of identity Parmesan cheese. The curing enzyme used is safe and suitable for cheese making with a long history of use in cheese making. No novel ingredients or processes are used in its manufacture.

The amount of aging time in Parmesan cheese does not contribute positively or negatively to the product's wholesomeness and nondeleteriousness. Aging of a Parmesan cheese has historical precedence only as a means to develop presumably desirable flavor and textural characteristics--two characteristics we have been able to obtain in the proposed Parmesan cheese of six months age.

**The Amount of Any New Ingredient to be Added:** We have made a Parmesan cheese aged for 6 months which has the taste, texture and nutritional characteristics of the current standard of identity Parmesan cheese with no change in basic ingredients required by the standard. Additionally, no novel ingredients, make procedures or manufacturing processes have been used. The only change made in the development of this product is the use of another enzyme--an enzyme commonly used in cheese making with an on-going history of safe and suitable use.

The product will still be comprised of pasteurized milk, salt, cultures and enzymes. We will only be using a different enzyme in addition to the one we use in our current Parmesan--which is aged for the presently required 10 months. We will be doing this to develop the characteristic Parmesan flavor notes at an earlier age. This enzyme is readily available, is widely used in the cheese industry, and has been affirmed as GRAS by FDA.

**Purpose of Effecting The Variation:** We are requesting this temporary permit to test market this shorter aged (6 month) Parmesan cheese so that we can collect data on customer and consumer acceptance. These data will be used in a subsequent petition to amend the current standard of identity for Parmesan cheese as to the aging requirement.

As stated earlier, we believe that with today's technology, it no longer is necessary to cure a Parmesan cheese for 10 months to obtain the taste, texture and functionality that are commonly expected from Parmesan cheese. We believe the testing that we have done to date, both internally and externally, validates this claim. This proposed market test period and the resultant customer and consumer feedback will further validate this claim.

Lastly, International Cheese Standards, as driven by the CODEX Alimentarius, will likely propose that the aging requirements standards on Parmesan (and other) cheeses be lessened or dropped completely. When and if such happens, regardless of U.S. Standards of Identity, U.S. cheese manufacturers will be non-competitive in a global marketplace if they do not have cheese that can compete cost effectively with non-domestic products unencumbered by an aging requirement.

**Statement of How Variation is of Potential Advantage:** The proposed variation in the aging requirement for Parmesan cheese benefits consumers and end users alike by ultimately lowering the cost of the product without a sacrifice in flavor, texture or nutrition. Aging and inventorying costs will be lower---creating an environment where total product costs will be lower--thereby allowing an opportunity for cheese manufacturers to better hold the line on costs to the ultimate consumer.

With lesser amounts of money being tied-up in inventory costs, 'barriers to entry' relative to the production of Parmesan cheese will also be lowered allowing for entry of new Parmesan cheese manufacturers--thereby creating new and additional competition in the marketplace.

**Proposed Labels:** Attached to this formal application please find our proposed labels for our Parmesan cheese aged for 6 months. The labels reflect each size in which we sell grated Parmesan cheese and request that the Temporary Permit cover. Since our current labels for Sartori Food Corporation Parmesan cheese make no reference to a 10 month aging, there is no need to reference, on the proposed labels, a change to the new 6 month aging time frame. (See Exhibit D)

**Period of Test:** Sartori Food Corporation desires to test the Parmesan cheese aged for 6 months in interstate commerce, involving both food service and industrial/ingredient channels of business, for a period of 15 months. We would like this period to begin

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immediately upon approval of this request. We need a period of this duration to adequately measure the dynamics of customer and consumer response among both our current customer base and potential new customers.

The nature and uncertainty of the food service and ingredients markets are often characterized by infrequent or irregular order patterns and cycles. Also, the myriad of end-use products that our Parmesan cheese is used in and the frequent customer testing (of new products) before (their) release as a retail product necessitate a testing period of this duration. This will allow for a large enough sample of marketplace conditions to validly evaluate customer and consumer marketplace acceptance.

**Probable Amount of Product Distributed:** The probable amount of Parmesan cheese aged for 6 months that we will distribute for testing purposes during this requested 15 month period will be up to 28,000,000 lbs. We need to test this product in two distinct channels, the food service and the industrial/ingredients markets--among customers of significant size that are national in distribution. Additionally, manufacturing and production efficiencies dictate a test of this size and scope.

**Areas of Distribution:** The Parmesan cheese aged for 6 months will be distributed and sold to food service and ingredients customers throughout the continental United States.

**Manufacturing Address:** The Parmesan Cheese aged for 6 months will be manufactured at the following cheese plants:

- 12 West Main, Plymouth, WI 53073
- 2 East Main, Plymouth, WI 53073
- 9001 North Lander Avenue, Hilmar, CA 95324

**Distribution in State of Manufacture:** The Parmesan cheese aged for 6 months will be distributed both in the States of Wisconsin and California, which are the states of its manufacture.

**Why Not Distributed in State of Manufacture:** Not applicable. Product will be distributed in states of manufacture.

**Reasons For Distribution into Other States:** With our current geographically dispersed customers, both food service and industrial, who sell their finished goods products (containing our product) throughout the United States, it would be physically impossible to limit the marketing of this product to a small geographic area. We can not control where our customers use and sell our product. There is, however, an advantage to this

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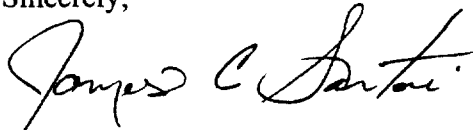


situation. It will allow this product to be adequately tested across a wide range of products, recipe applications and diverse consumer markets--thereby ensuring valid and projectible results.

In summary, we ask the FDA to consider favorably this application and the attached data and grant approval for a temporary permit to test market our 6 month aged Parmesan cheese. This would serve as an initial step to be followed by a later petition to amend the aging requirements found in the current Parmesan Standard 21CFR § 133.165

Please feel free to contact me at 920-893-6061 (Ext. 310) or my attorney, Martin J. Hahn of Hogan & Hartson, L.L.P. in Washington D.C. at 202/637-5926, for any additional information you might require.

Sincerely,



James C. Sartori  
President and CEO  
Sartori Food Corporation

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